#10 Rec 3/25/03

PATENT APPLICATION
ATTORNEY DOCKET NO.: 01017/37428

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Paszty *et al.*

Serial No: 09/867,274

Filed: May 29, 2001

For: Cystine-Knot Polypeptides: Cloaked-2 Molecules and Uses Thereof

Group Art Unit: 1632

Examiner: Scott D. Priebe, Ph.D.

I hereby certify that this paper is being deposited with the United States Postal Service as First Class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

March 13, 2003.

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ELECTION WITH TRAVERSE IN RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to a restriction requirement dated January 13, 2003, wherein the examiner asserted that pending claims 1-5, 8-36, and 38-62 were directed to 13 distinct inventions and required restriction. Reconsideration is requested. This response is timely filed in view of the petition for a one-month extension of time and attendant fee, both of which are being filed herewith.

REMARKS

I. Restriction

Citing 35 U.S.C. § 121, the examiner asserted that claims 1-5, 8-36, and 38-62 were drawn to 13 distinct inventions:

Group I:	Claims 1-5, 11, and 52-54, drawn to a nucleic acid encoding a mouse or human cloaked-2 polypeptide;
Group II:	Claims 8 and 10, drawn to a recombinant method of making a mouse or human cloaked-2 polypeptide;

Group III:	Claims 9, 13-23, 46-51, and 55-56, drawn to a mouse or human cloaked-2 polypeptide;
Group IV:	Claim 12, drawn to a cell-based assay to identify a compound that inhibits activity of a mouse or human cloaked-2 polypeptide;
Group V:	Claim 12, drawn to a cell-based assay to identify a compound that inhibits expression of a mouse or human cloaked-2 polypeptide;
Group VI:	Claims 24-26, 29-36, 38-42, and 44, drawn to an agent (e.g., an antibody) that specifically binds a mouse or human cloaked-2 polypeptide;
Group VII:	Claims 27 and 45, drawn to a hybridoma that produces an antibody that specifically binds a mouse or human cloaked-2 polypeptide;
Group VIII:	Claims 28 and 58, drawn to a method of detecting a mouse or human cloaked-2 polypeptide with an antibody;
Group IX:	Claim 43, drawn to a method of treatment with an agent (e.g., an antibody) that specifically binds a mouse or human cloaked-2 polypeptide;
Group X:	Claims 57 and 59, drawn to a method of treatment with a mouse or human cloaked-2 polypeptide;
Group XI:	Claim 60, drawn to an assay for identifying a compound that binds a mouse or human cloaked-2 polypeptide;
Group XII:	Claim 61, drawn to a method of treatment with a nucleic acid encoding a mouse or human cloaked-2 polypeptide; and
Group XIII:	Claim 62, drawn to a non-human transgenic animal comprising a nucleic acid encoding a mouse or human cloaked-2 polypeptide.

II. Election

The applicants hereby elect Group I, which includes claims 1-5, 11, and 52-54, drawn to a nucleic acid encoding a mouse or human cloaked-2 polypeptide, a vector containing the same, a host cell thereof, and a composition comprising the same, with traverse.

III. Argument

The examiner has restricted the pending claims into thirteen groups. Although the examiner acknowledged that the subject matters of the pending claims are related, and therefore not independent for purposes of restriction practice, the examiner asserted that the applicants are claiming thirteen distinct inventions. In response, the applicants respectfully traverse. The applicants provide general comments applicable to all aspects of the instant restriction, and provide comments relevant to the restriction of particular claim groups in appropriately titled subsections below.

The applicants request that the restriction requirement be reconsidered because the examiner has not shown that a serious burden would be required to examine the claims of Groups I-XIII. M.P.E.P. § 803 provides:

> If the search and examination of an application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.)*

Thus, for a restriction to be proper, the examiner must satisfy the following two criteria: (1) that independent and distinct inventions are being claimed (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. *See* M.P.E.P. § 803.

The applicants submit that the examiner has not established that a serious burden would be imposed on the patent office if all 59 claims under consideration were searched and examined together. Although separate classification of claim groups is often cited in support of a *prima facie* basis for proper restriction, the applicants note that claim 12, the only claim of Group IV, is classified in class 435, subclass 7.21 and that same claim, claim 12, is the only claim of Group V, which has been classified in class 435, subclass 6. The distinct classification of Groups IV and V, each containing the same single claim, indicates that the classification of the claims has been arbitrary. Moreover, the claims under consideration define subject matter that directly or indirectly relates to biomolecules of defined sequences.

These sequences are searched using electronic databases and do not primarily rely on the classifications identified in the office action. The results of these searches contribute to the shape of the examination. In view of the subject matters of the claims under consideration, the applicants submit that the examiner has failed to establish that a serious burden would be imposed if all of these claims were searched and examined in the instant application. Accordingly, the restriction requirement has been overcome and should be withdrawn.

A. The restriction between claims drawn to combinations and claims drawn to subcombinations thereof should be withdrawn

The examiner imposed restrictions between (1) the claims of Group I and the claims of Group XIII, (2) the claims of Group III and the claims of Group XIII, and (3) the claims of Group VI and the claims of Group VII, in each case asserting that the restricted claims groups were drawn to distinct combinations and subcombinations thereof. (*See* Office Action at pp. 4-6.) Under M.P.E.P. § 806.05(c), two-way distinctness must be shown and reasons for insisting on restriction are necessary. The classifications of the claims in these groups was arbitrary, as established above, and the examiner did not provide any other reason for insisting on restriction between claim groups assertedly related as combination-subcombination. For this reason alone, the applicants submit that the restrictions are improper and should be withdrawn.

Beyond the preceding dispositive point, the applicants submit that the examiner has not established two-way distinctness for any of the combination-subcombination restrictions. With reference to the restriction between claims of Groups I and XIII, the examiner maintained that "the combination as claimed does not require the particulars of the subcombination as claimed because the transgenic animals can comprise nucleic acid encoding either mouse or human cloaked-2 polypeptide, or any of the derivatives of each embraced by claim 1." (*Id.* at p. 4.) Applicants are confused by this statement. The examiner acknowledges that claim 62, the sole claim of Group XIII, is dependent on claim 1. Dependent claim 62 incorporates each limitation of the claim from which it depends as a matter of law. Consequently, claim 62, apparently identified as the "combination" claim by the examiner, does in fact require the particulars of the "subcombination" defined by the claims (e.g., claim 1) from which it depends. The applicants do note that claim 62 is a multiple dependent claim (i.e., depending from any of claims 1-3). If the examiner is asserting that this multiple dependency is the basis for the assertion that combination claim 62 does not require the particulars of the claimed subcombination, such as the

subcombination of claim 1, the applicants note their disagreement. A multiple dependent claim is dependent in the alternative on each of the base claims. Thus, multiple dependent claim 62 is drawn to three "combinations," which correspond to three "subcombinations," using the examiner's terminology. In each case, the definition of the "subcombination," whether defined by claim 1, 2, or 3, is exactly the same in both the "subcombination" claim and the "combination" claim. In terms of M.P.E.P. § 806.05(c), claim 62 is drawn to AB_{sp} when considered, e.g., in terms of its dependency on claim 1 and claim 1 itself is drawn to B_{sp}, where B_{sp} is the specific subcombination of claim 1. Thus, the facts align with the scenario described in M.P.E.P. § 806.05(c)II, which provides that restriction is improper. The circumstances giving rise to restriction, as defined in M.P.E.P. § 806.05(c)I, involve a subcombination of B_{sp}, and a combination of AB_{br}, where B_{br} is a broad recitation of the subcombination. Where, as here, the asserted combination claim is a dependent claim, there can be no difference in the scope of the "subcombination" defined by either claim.

For these reasons, the applicants respectfully request that the restrictions between (1) the claims of Group I and the claims of Group XIII, (2) the claims of Group III and the claims of Group XIII, and (3) the claims of Group VI and the claims of Group VII, are improper and should be withdrawn.

B. The restriction between claims drawn to methods of making a product and the product should be withdrawn

The examiner imposed restriction between the claims of Group II and the claims of Group III, asserting that the restricted claims groups are distinct because the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). (*See* Office Action at p. 4.)

The examiner's stated basis for restricting a method of making the polypeptide with the polypeptide of the invention was that inventions II and III "are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the cloaked-2 polypeptide could be produced from mouse or human tissue which endogenously produces it." (*See* Office Action at p. 4.) The applicants note that the sole support for restricting the claims of Groups II and III is the statement that "the cloaked-2 polypeptide could be produced from mouse or human tissue which endogenously produces it," inserted into Form

Paragraph 8.18. The examiner is effectively asserting that production of cloaked-2 polypeptide from mouse or human tissue endogenously producing it is materially different from the claimed production method. That method, as recited in claim 8 of Group III, involves producing the polypeptide by culturing a host cell ultimately comprising a nucleic acid encoding cloaked-2. The statement that cloaked-2 polypeptide could be produced from mouse or human tissue which endogenously produces it does not even distinguish the claimed method, let alone define a materially different method of production. Nowhere in either claim 8 or claim 10, the only claims of Group III, is there a limitation that the host cell be incapable of endogenous expression of cloaked-2. Thus, the examiner has failed to establish a *prima facie* case in support of restricting the claims of Group II and the claims of Group III.

For the preceding reasons, the applicants submit that the restriction between the claims of Groups II and III is improper and should be withdrawn.

C. The restriction between claims drawn to products and claims drawn to processes of using such products should be withdrawn

Restrictions were imposed (1) between the claims of Groups XII and Groups I, II, and V, (2) between the claims of Groups III and Groups X and XI, and (3) between the claims of Groups VI and Groups VIII, IX and XI, notwithstanding the examiner's acknowledgement that the claims were related (i.e., not independent). For each of these restrictions, the examiner asserted that the claims were related as product and process of use and that the claims in those groups were distinct because the product could be used in materially different processes of use under M.P.E.P. § 806.05(h). In particular, the restriction between the claims of Group I and the claims of any of Groups II, V, and XII was supported by maintaining that the nucleic acid products of Group I could be used in any one of the methods of Groups II, V, XII, and also for detecting clones of cloaked-2 nucleic acid or identifying tissue expressing cloaked-2 mRNA. (*See* Office Action at pp. 3-4.) With respect to the claims of Groups III and each of X and XI, the examiner asserted that the polypeptides of Group III could be used in the inventions of Groups X or XI, as well as being used to make the antibodies of Group VI. (*See* Office Action at p. 5.) The restriction between the claims of Group VI and the claims of any of Groups VIII, IX and XI, was supported by the assertion that the binding agents of Group VI could be used in any of the methods of Groups VIII, IX, or XI, as well as being used for affinity purification of cloaked-2 polypeptides. In each case, the examiner

effectively asserted that the claimed products could be used in materially different processes of use under M.P.E.P. § 806.05(h).

In accordance with M.P.E.P. § 806.05(h), the examiner bears the burden of providing an example in support of the asserted bases for restriction. In each of the three above-referenced restrictions (i.e., Group I *versus* Groups II, V, and XII; Group III *versus* Groups X and XI; Group VI *versus* Groups VIII, IX and XI), the examiner has not provided an example that establishes materially different uses for the products. As noted above, the classifications imposed on the claims under consideration are arbitrary. Therefore, the applicants submit that the assertedly distinct classifications of claims in the various groups do not establish that the methods of use are materially different. The examiner has provided no other basis for the restriction and, hence, has provided no example of the products (nucleic acids of Group I, polypeptides of Group III, or binding agents of Group VI) being used in materially different processes. For these reasons, the applicants submit that the restrictions between (1) claims of Group I and claims of Groups II, V, and XII, (2) claims of Group III and claims of Groups X and XI, and (3) Group VI and claims of Groups VIII, IX and XI, have been overcome and the restrictions should be withdrawn.

D. The restriction between claims of Group I and claims of Groups III-IV and VI-XI is improper and should be withdrawn

The examiner restricted the claims of Group I and the claims of Groups III-IV and VI-XI, asserting that the subject matters of these claims are unrelated. In support of the assertion, the examiner stated that "the nucleic acid of invention I is not used in any of the methods of inventions IV, VIII-XI, is not present in the hybridoma of invention VII, and does not share a common structure or function with cloaked-2 protein or agents which bind cloak-2." (*See* Office Action at p. 6.) The examiner continues, purporting to demonstrate the unrelatedness of the polypeptide subject matter of claims in Group III and the methods of claims in Groups IV-IX and XII, as well as the binding agents of the claims of Group VI and the methods of claims in Groups II, IV, V, X, and XII, the transgenic animals of invention XIII. Finally, the examiner asserts that the subject matter of claims VII and XII are unrelated to any claimed method, without further identification. In response, the applicants note their confusion and traverse.

The applicants initially note that the examiner is maintaining that the nucleic acid claims of Group I are "unrelated" to the claims of Group IV. (*See* Office Action at p. 6.)

Elsewhere in the Office Action, the examiner stated that "[i]nvention I and inventions II, V and XII are related . . . ." (Office Action at p. 3.) The sole claim in each of Groups IV and V is claim 12. Thus, the examiner is simultaneously asserting that the nucleic acid claims of Group I are both related and unrelated to the very same process of claim 12. The reasoning behind this restriction appears illogical and cannot sustain the requirement to restrict.

For these reasons, the applicants submit that the restriction between the claims of Group I and the claims of Groups III-IV and VI-XI is improper and should be withdrawn.

CONCLUSION

For the foregoing reasons, applicants request reconsideration and withdrawal of the restriction requirement. Should the examiner have any questions or comments regarding this response or the application, the examiner is invited to contact the undersigned at the number indicated.

Respectfully submitted,

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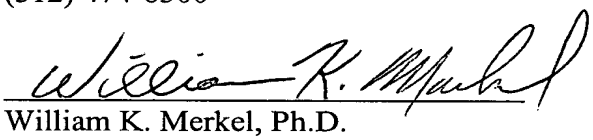
By 

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March 13, 2003